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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,461	02/12/2004	Erika Hawkins	341.022US1	2264
21186 7590 08/06/2008 SCHWEGMAN, LUNDBERG & WOESSNER, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402				
EXAMINER HANLEY, SUSAN MARIE				
ART UNIT		PAPER NUMBER		
1651				
MAIL DATE		DELIVERY MODE		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/777,461

**Applicant(s)**

HAWKINS ET AL.

**Examiner**

SUSAN HANLEY

**Art Unit**

1651

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-56, 63-67 and 69-73 is/are pending in the application.
- 4a) Of the above claim(s) 2, 4, 5, 9-11, 16-21, 25-32, 37, 45, 46, 48, 53, 63 and 64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 6-8, 12, 14, 15, 22-24, 33-36, 38-44, 47, 49-52, 54-56, 65-67 and 69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4/9/08

- 4) ☐ Interview Summary (PTO-813)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment and reply filed 4/9/08 are acknowledged.

Claims 1-12, 14-56, 63-67 and 69-73 are pending.

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-42, 56 and 69; and the following specie election:

A. Quenching agent for the first or second enzyme-mediated reaction: a sequestering agent that is a nonionic detergent;

B. First enzyme-mediated luminescence reaction: Renilla reniformis luciferase-mediated;

C. Second enzyme-mediated luminescence reaction: Photinus pyralis luciferase-mediated;

in the reply filed on 1/31/07 is again acknowledged. Applicants' traversal was found persuasive, in part. Groups I and II (method and kit) were rejoined insofar as they read on the elected species.

Claims 2, 4, 5, 9-11, 16-21, 25-32, 37, 45, 46, 48, 53, 63 and 64 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/31/07.

Claims 25 and 26 are drawn to a peroxidase-mediated luminescence reaction and a horse radish peroxidase-mediated luminescent reaction, respectively. In the first Office action, these claims were inadvertently not accounted for on the PTO-326. In the Office action mailed 12/11/07, claim 25 was objected to and claim 26 was again not listed. Based on the specie election for a first enzyme-mediated luminescence reaction and the identification of said specie elections in the previous Office actions, the peroxidase mediated luminescent reaction was clearly a non-elected specie. The examiner apologizes for the oversight. However, the claims should have been withdrawn initially. Clearly, there has been no substantive examination on these specie for the purposes of prior art or enablement. Examination will be extended to this specie when the anthozoan-mediated luminescent reaction specie is free from rejection.

Claims 1, 3, 6-8, 12, 14, 15, 22-24, 33-36, 38-44, 47, 49-52, 54-56, 65-67 and 69 remain under examination. Claims drawn to an anthozoan luciferase or a peroxidase will be examined insofar as they read on an anthozoan luciferase.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawal of Rejections***

The objections and rejection not explicitly restated below are withdrawn due to Applicant's response in the amendment filed 4/9/08.

***Drawings***

The drawings filed 4/9/08 overcome the objection to Figure 5.

***Response to Arguments***

***Claim Rejections - 35 USC § 112***

Claims 1, 3, 6-8, 12, 14, 15, 22-24, 33-36, 38-44, 47, 49-52, 54-56, 65-67 and 69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for determining luminescence energy produced by a first and second luciferase-mediated luminescence reaction wherein at least one of said luciferases is anthozoan and the luminescence generated by the anthozoan luciferase is selectively quenched by coelenterazine hh methyl ester; colored compounds that absorb red, yellow, green and blue wavelengths of light as disclosed on page 31, lines 11-19 of the specification; and nonionic detergents that are not polyethylene glycol octylphenylether or polyoxyethylene sorbitan monolaurate prior to initiating the second luminescent reaction; and determining the luminescence produced by the second reaction; and a kit thereof, does not reasonably provide enablement for said method or kit wherein the first enzyme mediated reaction is provided by any possible substrate analog inhibitor for an anthozoan luciferase or a protected coelenterazine or any possible colored compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Applicant argues that it is within the skill of the art to identify specific substrate analog inhibitors, specific nonionic detergents and specific colored compounds other than those in the working examples in the specification, that are selective quench reagents for an anthozoan luciferase-mediated luminescence reaction. Applicant asserts that Sherf et al. (U.S. Patent No. 5,744,320), a reference cited against the claims under § 102(b)/§ 103, provides evidence that the identification of selective quench reagents is within the skill of the art [sic].

Applicant's argument has been considered but is non-persuasive. The point of novelty for the invention is the selectivity of the quenching of the bioluminescent reactions. Hence, the complexity of determining a successful quenching agent is two-fold because the response of both the first and second reporters to a potential quencher must be considered to provide for a successful assay. Regarding Applicant's assertion that Sherf provides evidence that the identification of selective quench reagents is within the skill of the art, Sherf is directed to reporter dual assays that are based on firefly luciferase as the first reporter and Renilla luciferase as the control. Sherf does not address the discovery of selective quench agents for the reverse pairing. The design of enzyme inhibitors requires detailed knowledge about the active site of an enzyme. Without some disclosure regarding the active site, the skilled artisan could not predict which compounds based on the disclosed generic structure would be inhibitors and not substrates for the anthozoan luciferase. Hence, the skilled artisan would have to resort to trial and error testing of compounds to find inhibitors and not substrates. Such a trial and error process clearly amounts to undue experimentation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/  
Examiner, Art Unit 1651

/Sandra Saucier/  
Primary Examiner, Art Unit 1651